UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

TAMMY ALLEN, PERSONAL REPRESENTATIVE OF THE ESTATE OF NORMAN ALLEN Plaintiff, v. UNITED STATES OF AMERICA Defendant.	)	Case No. 05-11463-DPW

DEFENDANT'S TRIAL MEMORANDUM

I. INTRODUCTION

This court has jurisdiction over matters that conform to the requirements of the Federal Tort Claims Act, a congressional waiver of sovereign immunity that is to be strictly construed. Under 28 U.S.C. § 1346(b) the United States is the proper defendant in a matter that is properly brought under the Federal Tort Claims Act. A plaintiff must satisfy the conditions for bringing an action under the Federal Tort Claims Act, including filing an administrative claim. Contrary to plaintiff's trial memorandum, there is no concept of a public employer within the meaning of the Federal Tort Claims Act. Michael Kelly, M.D. ("Dr. Kelly") was not an employee of the United States, but is deemed to be an employee for purposes of this case under the Federally Supported Health Centers Assistance Act of 1992, 42 U.S.C. § 233(g) and the Federal Tort Claims Act, 28 U.S.C. §§ 1346(b) and 2671-2679.

Greater Lawrence Family Health Center, Inc. is a grantee under the federal community health centers program, 42 C.F.R. § 51c.301. The statutory basis for the program is Public Health Service Act § 330, 42 U.S.C. § 254. 42 C.F.R. § 51c.101. The national purpose of the program is "to increase access to comprehensive primary and preventive health care and to

improve the healthcare status of underserved and vulnerable populations." Http://bphc.hrsa.gov/chc/programexpectations.htm. The physicians and staff of the community health centers like Greater Lawrence Family Health Center, Inc. perform a public service for the members of society whose low income or community circumstances result in lack of adequate service by the private, for-profit, health care system. There is a federal requirement for a health center governing board to include a majority of members who are or will be served by the center. 42 C.F.R. § 51c304. There may be special difficulties in the daily effort of the health center staff to serve populations within a socioeconomic underclass. The Court should consider the adverse effect of an unwarranted claim of malpractice on a physician or those similarly situated who serve in a community health center program, a program whose central purpose is to alleviate the harshness of this society's difficult problem pertaining to provision of health care. The congressional decision to provide malpractice coverage for many health centers and their staff through the Federal Tort Claims Act (even though they are not federal employees) does not diminish the public policy need to recognize the public service role of, and avoid disheartening or discouraging physician participation in, the community health center program.

II. CAUSATION

A doctor is not held to the standards of perfection or excellence, but he must be more than minimally competent. He must know what the average physician would know, and must practice his specialty in the manner of the average qualified physician. *Brune v. Belinkoff*, 354 Mass 102, 109 (1968). A doctor is held to the standard of care and skill of the average member of the profession practicing that specialty, taking into account the advances of the profession and

the resources available to him. *Id*. Dr. Kelly met that standard of care while treating Norman Allen ("Mr. Allen") during 1997 through 1999.

The plaintiff offers an expert witness who claims that during 1997 through 1999 Dr. Kelly breached the standard of care by not screening Mr. Allen for colorectal cancer. The majority of average risk patients, however, between ages 50 to 80 years who have a relationship with an average qualified primary care physician would not have been screened for colorectal cancer between 1997 and 1999, when Dr. Kelly cared for Mr. Allen. *See* Affidavit of James Richter, M.D. ¶14. Medicare has covered colorectal cancer screening tests and procedures since 1998, but use of this benefit has been low. *Id.* Medicare claims from 1998 - 2002 suggest that only about 31% of beneficiaries have ever had any colorectal cancer-screening test. Between 1998-2001, the relevant period for this case, Medicare only covered screening of high-risk patients. Medicare and Medicaid did not begin to routinely cover the cost of the procedure until 2001. Despite plaintiff's medical expert's claims, Mr. Allen was not known to be in a high risk patient group. *Id.*

The majority of Mr. Allen's visits to Dr. Kelly were focused on his urgent muscular, sleep and emotional issues leaving little opportunity for addressing other health improvement topics. *Id* at ¶ 11. No where in the Greater Lawrence Community Family Health Center, Inc. record is there any indication that Mr. Allen informed Dr. Kelly that he had a family history of colorectal cancer. *Id* at ¶ 4. In fact, the medical record demonstrates that Mr. Allen was asked specifically whether he had a family history of cancer and he provided no information about his father's alleged history of colon cancer. Instead, the record demonstrates that Mr. Allen informed Dr. Kelly that his family history only included his father's myocardial infarctions and

his mother's asthma. The only place in Mr. Allen's medical record that indicates any family history of colorectal cancer can only be found after he left Dr. Kelly's care.

This central fact undermines plaintiff's counsel's medical expert who assumes that Mr. Allen informed Dr. Kelly in the Greater Lawrence Community Health Center that he had an alleged family history of colorectal cancer. Plaintiff's medical expert also attempts to equate the recommendations of several national professional organizations with ther standard of care. This is not only contrary to the case law, but also to the and to the standard practice at the time those recommendation were promulgated. It is self-evident that the promulgation of recommendations by a national medical organization does not instantly change the standards of practice. Those recommendations are merely goals for the medical field and then sometime later they might become the standard of care.

During the 1997 through 1999 time period, colorectal cancer screening was not required even after Mr. Allen turned age 50 and Dr. Kelly's actions complied with the standards of care for the average qualified primary care physician. *Id* at ¶ 16 and 17. This is especially given that Mr. Allen repeatedly presented himself at the health center with numerous urgent needs and complex emotional and other physical conditions requiring priority and treatment and did not use the health center for overall proactive health maintenance. Dr. Kelly properly responded to and prioritized the needs as any average physician would do during the time period in question.

Moreover, if Dr. Kelly had ordered colorectal screening for Mr. Allen in April of 1999 or when Dr. Kelly received Dr. Simms' report that Mr. Allen reports gastrointestinal bleeding, Mr. Allen's chances of survival from colon cancer could not have been improved. *See* Affidavit of James Talcott, M.D. ¶ 8, 13 and 14. Had Dr. Kelly ordered colorectal screening for Mr. Allen in

1998, when Mr. Allen was 50 years old, the subsequent identification of cancer in the colon would not have changed his prognosis. *Id.* Even at the time when cancer was later detected, it was not identified in a rectal examination performed in Mr. Allen's GI workup. *Id.*

Furthermore, evidence shows that Mr. Allen's cancer could not have been detected with the test the plaintiff's expert states Dr. Kelly should have performed. For example, digital rectal exam would not have located the cancer growth located in Mr. Allen's rectum. The cancer was located eight centimeters into Mr. Allen's colon which is beyond the reach of a physician's finger sensing zone. *Id* at ¶ 5 and 7. Mr. Allen's cancer was diagnosed a little over eight centimeters from the anal verge so the cancer would not have been diagnosed by a rectal exam. And, in fact, was not identified in rectal examinations performed in his GI work up. *Id* at ¶ 7.

At surgery on December 1, 1999, Mr. Allen was found to have cancer in one of six sampled lymph nodes, resulting in the diagnosis of Stage III colon cancer. *See* Affidavit of James Talcott at ¶ 5. Mr. Allen's cancer had already metastasized. *Id* at ¶12. A large number of cancer cells are required for medical detection. *Id* at ¶10. A cc of cancer cells, which is comprised of 10 to 100 billion cells, is generally regarded as the minimum size for detection. *Id.* For a single malignant cell to progress by cell divisions or "doubling" to achieve that mass require approximately 25 to 34 cell divisions. *Id.* A cancer which doubles within a month, which is a rapid rate for a colon cancer, would have first invaded the lymph node 25 to 34 months before it was detected in late 1999 to achieve a 1 cc size, which would establish its origin in 1996 or 1997. Therefore, screening in 1998 or 1999 even if it diagnosed the cancer, would not have preceded the establishment of a lymph node metastasis.

Virtually all solid tumors, such as rectal cancer, are curable only when the cancer has not spread to other parts of the body, or metastasized; surgery, or in some cases radiation therapy, results in the removal or destruction of all cancer cells in the body only if the cancer has not spread beyond the selected treatment target. Because Mr. Allen's cancer had already metastasized in the lymph node sometime during the period 1996 and 1997, surgery would have not been curative. *Id* at ¶8 and 12.

In short, during the time period 1997 and 2000, Dr. Kelly conformed to the standards of practice of an average qualified primary care physician, to a reasonable degree of medical certainty, in the care provided to Mr. Allen. *See* Affidavit of James Richter, M.D., ¶1. Even if the court found he did not conform to the standards of practice of an average qualified primary care physician during that period, by not providing colorectal cancer screening to Mr. Allen, Mr. Allen's prognosis and outcome would not have been any different. *See* Affidavit of James Talcott, M.D., ¶11, 12, 13 and 14.

Finally, Mr. Allen's medical condition, physical health, and psychological status was devastated by the lifestyle he led. The evidence will that show Mr. Allen consumed large quantities of illegal as well as prescription drugs, three or four cases of beer per week, fifteen cups of coffee per day, two to three packs of cigarettes per day, had a poor diet and that his favorite activity was watching television. Additionally, the evidence will also show domestic violence was a part of the Allen household. To be sure, the vast majority of Mr. Allen's visits to Dr. Kelly were focused on his urgent muscular, sleep and emotional issues leaving little opportunity for addressing other health improvement topics. This lifestyle also affected Mr. Allen's ability to effectively communicate to Dr. Kelly, to maintain any reasonable possibility of

achieving good health and to even follow through on health improvement advice Dr. Kelly offered Mr. Allen. Moreover, not only would this drug induced lifestyle affect his health and memory, but it would also mask communication of symptoms that may indicate that further testing is warranted.

The evidence will also show that Mr. Allen's visits to and contact with the Greater Lawrence Family Health Center was to obtain pain medications and not for general physical examinations. Dr. Kelly's response to the variety and multitude of urgent needs expressed by Mr. Allen was appropriate. Dr. Kelly responded to the most urgent needs by providing prescriptions, making appropriate referrals and tests to address those urgent needs. The evidence will show that Mr. Allen's lifestyle would provide him an incentive to avoid blood tests, which could reveal his illegal drug abuse.

The evidence will show that physicians, including Dr. Kelly, at the Greater Lawrence Community Health Center routinely provided lab slips to patients for regular screening. Unfortunately, if the patient did not follow through with the lab tests, there is no documentation of the lab test being recommended in the medical file. The only evidence that a lab test was recommended would be provided when the results of the test were forwarded to the physician. The evidence suggests that Dr. Kelly provided Mr. Allen with lab test referrals but Mr. Allen did not follow through with presenting himself at the laboratory.

Defendant's objection to Plaintiff's use of informed consent theory.

Contrary to the plaintiff's arguments, the legal requirements of informed consent is inapplicable in a case where the plaintiff alleges that a medical doctor failed to screen and diagnose colon cancer. *Roukounakis v. Messer*, 63 Mass.App.Ct. 482 (2005), citing *Bays v. St. Luke's Hosp.*, 63 Wash.App. 876, 883 (1992). ("The duty to disclose does not arise until the physician becomes aware of the condition by diagnosing it.")

EXPECTED EVIDENTIARY ISSUES:

No unusual evidentiary issues are anticipated at this time except that Defendant's may object to the relevance of evidence demonstrating extensive use of illegal drugs by all members of the Allen family. A central contention of the United States' defense is that Mr. Allen's extensive use of illegal drugs hampered his ability to communicate, remember, masked physical symptoms, provided an incentive for him to avoid blood tests, provided him an incentive to appear at the Greater Lawrence Community Health Center for prescription narcotics and caused a variety of other symptoms including urgent sleep and emotional issues, thereby leaving little opportunity for Dr. Kelly to address other systemic health care issues. The current use of illegal drugs by Ruth, Steven, and Tammy Allen coupled with other testimonial evidence at trial will demonstrate that Mr. Allen lived and pursued a lifestyle that included an extensive use of illegal drugs during the 1996 through 1999 time period. The evidence regarding the Allen family's extensive past and present drug abuse also demonstrates Ruth, Tammy and Steven Allen's testimony that they never witnessed Mr. Allen using illegal drugs incredible. Plaintiff's damages contentions are contradicted by evidence about the employment and income status of Norman Allen, Ruth Allen, Steven Allen and Tammy Allen.

List of Witnesses

1. James Richter, M.D.
Harvard Medical School
Massachusetts General Hospital
Internal Medicine and Gastroenterology
MGH Gastroenterology Associates, Blake 4
55 Fruit Street
Boston, Massachusetts 02114

2. James A. Talcott, M.D.
Harvard Medical School
Massachusetts General Hospital
Internal Medicine and Medical Oncology
The MGH Cancer Center, Center for Outcomes Research
55 Fruit Street, HO1-107
Boston, Massachusetts 02114

3. Glennon O'Grady
Medical Director, Greater Lawrence Family Health Center, Inc.
34 Haverhill Street
Lawrence, Massachusetts

4. Michael Kelly, M.D.
32 Old Mill Street
Goshen, Connecticut

5. Gary Ketchen
818 Ohio Street, Apt. 20
Bangor, Maine 04401

6. Jason Conant or designee
Massachusetts State Police Trouper
Drug Task Force, Lawrence, Massachusetts

7. The United States reserves the right to call the medical student and now medical doctor who obtained Norman Allen's medical family history on January 5, 1996.

Depositions to be used at trial:

The defendant submits the depositions of Steven Allen, Ruth Allen and Tammy Allen as evidence at trial to establish the numerous inconsistencies the Allen family provided under oath. The defendant also will use those depositions for impeachment in cross examination.

Exhibits to be introduced without objections:

The defendant anticipates introducing the following exhibits at trial:

501. Norman Allen's medical record.

502. Curriculum Vitae of all defendant's medical experts.

503. Financial documents regarding Steven Allen including tax returns and other records that may be obtained before or during trial.

504. Any financial records of Ruth Allen that are either obtained by subpoena or from the plaintiff's counsel before or during trial.

505. Any financial records of Tammy Allen that are either obtained by subpoena or from the plaintiff's counsel before or during trial.

506. Lab slip from the Greater Lawrence Family Health Center, Inc.

507. Documents or records that reveal the applications for medicare eligibility, or free medical care, or for any medical services obtained by the Allen family members during 1997 through 2002.

508. Any and all records and documents demonstrating method of payment for medical services provided to Allen family members.

509. Any and all records and documents relating to Steven Allen's employment at United Van Lines.

Marked items to be offered at trial to which the plaintiff has reserved the right to object:

The defendant does not have any marked items to which the plaintiff has reserved the right to object at this time. The defendant does not anticipate any objections by plaintiff for the exhibits marked above.

Notice of defendant's intent to cross examine:

The defendant has given notice of its intent to cross examine plaintiff's expert witness. The defendant also reserves the right to cross examine any additional expert or non expert witnesses that the plaintiff may call.

Findings of fact and conclusions of law

The defendant attaches as a separate document the Defendant's Proposed Additional or Substitute Finding of Facts and Conclusions of Law.

Respectfully submitted,

MICHAEL J. SULLIVAN
United States Attorney

Dated: February 20, 2007

By: /s/ Christopher Alberto

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